

Sheet 1 of 1

Substitute Form PTO-1449  
(Modified)U.S. Department of Commerce  
Patent and Trademark OfficeAttorney's Docket No.  
01948-061001Application No.  
09/778,013Information Disclosure Statement  
by Applicant

(Use several sheets if necessary)

(37 CFR §1.98(b))

Applicant  
Terry Strom *et al*Filing Date  
February 6, 2001

Group Art Unit

~~1645~~ 1637

TECH CENTER 1600/2900

OCT 31 2002

## U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA						
	AB						
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## Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
J.T	AL	WO 99/15700	01.04.1999	WIPO	C12Q	1/68	✓	
	AM							
	AN							
	AO							
	AP							

## Other Documents (include Author, Title, Date, and Place of Publication)

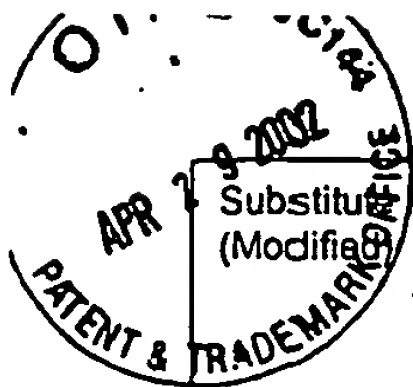
Examiner Initial	Desig. ID	Document
J. TW	AQ	Gillian M. Griffiths, et al. <i>Granzyme A and perforin as markers for rejection in cardiac transplantation</i> . Eur. J. Immunology 27:687-692, 1991.
J. TW	AR	Benoit Guerette, et al. <i>Increased Granzyme B mRNA after alloincompatible myoblast transplantation</i> . Transplantation 60(9):1011-1016, 1995.
J. TW	AS	XP002199955. Database Accession No. U19463. 11 February 1995.
	AT	

Examiner Signature

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Substitute Disclosure Form (PTO-1449)

Substitute Form PTO-1449  
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Patent and Trademark OfficeAttorney's Docket No.  
01948-061001Application No.  
09/778,013**RECEIVED****Information Disclosure Statement****by Applicant**

(Use several sheets if necessary)

(37 CFR §1.98(b))

Applicant  
Terry Strom, et al.

MAY 02 2002

Filing Date  
February 6, 2001

Group Art Unit

1645/1637 TECH CENTER 1600/290

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
J.T	AA	5,569,588	Oct. 29, 1996	Ashby et al	—	—	—
—	AB	5,213,961	May 25, 1993	Bunn et al	—	—	—

**Foreign Patent Documents or Published Foreign Patent Applications**

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							Yes	No

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
J.T	AC	Cassol, et al. <i>Primer-mediated Enzymatic Amplification of Cytomegalovirus (CMV) DNA</i> . J. Clin. Invest. 83:1109-1115 (Apr. 1989).
" "	AD	Eisen, et al. <i>Cluster analysis and display of genome-wide expression patterns</i> . Proc. Natl. Acad. Sci. USA 95:14863-14868 (1998).
" "	AE	Meyer-Konig, et al. <i>Human Cytomegalovirus Immediate Early and Late Transcripts in Peripheral Blood Leukocytes: Diagnostic Value in Renal Transplant Recipients</i> . Journal of Infection Diseases 171:705-709 (1995).
✓ " "	AF	Lipman, et al. <i>Hightened Intragraft CTL Gene Expression in Acutely Rejecting Renal Allografts</i> . Journal of Immunology 152:1520 (1994).
" "	AG	Perou, et al. <i>Molecular portraits of human breast tumors</i> . Nature 406:747-752 (2000).
" "	AH	Ross, et al. <i>Systematic variation in gene expression patterns in human cancer cell lines</i> . Nature Genetics 24:227-235 (2000).
" "	AI	Rush, et al. <i>Sequential protocol biopsies in renal transplant patients</i> . Transplantation 59(4):511-514 (1995).
" "	AJ	Rush, et al. <i>Histological findings in early routine biopsies of stable renal allograft recipients</i> . Transplantation 57(2):208-211 (1994).
" "	AK	Wright, et al. <i>The polymerase chain reaction: miracle or mirage? A critical review of its uses and limitations in diagnosis and research</i> . Journal of Pathology 162:99-117 (1990).
" "	AL	Abraham, et al. <i>Transfection of the human heme oxygenase gene into rabbit coronary microvessel endothelial cells: Protective effect against heme and hemoglobin toxicity</i> . Proc. Natl. Acad. Sci. USA 92:6798-6802 (July 1995).
" "	AM	Agarwal, et al. <i>Induction of heme oxygenase in toxic renal injury: A protective role in cisplatin nephrotoxicity in the rat</i> . Kidney International 48:1298-1307 (1995).
" "	AN	Agarwal, et al. <i>Gas-generating systems in acute renal allograft rejection in the rat</i> . Transplantation 61(1):93-98 (1996).
" "	AO	Agarwal, et al. <i>Renal response to tissue injury: Lessons from heme oxygenase-1 gene ablation and expression</i> . J. Am. Soc. Nephrol. 11:965-973 (2000).
" "	AP	Agodoa et al. <i>Assessment of structure and function in progressive renal disease</i> . Kidney International 52(Supp.63):S144-S150 (1997).
J.Z	AQ	Aizawa, et al. <i>Heme Oxygenase-1 is upregulated in the kidney of angiotensin II-Induced Hypertensive Rats</i> . Hypertension 35:800-806 (2000).

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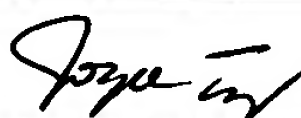
Substitute Form PTO-1449 U.S. Department of Commerce Patent and Trademark Office <b>Information Disclosure Statement</b> <b>by Applicant</b> (Use several sheets if necessary) (37 CFR 1.98(b))	Attorney's Docket No. 01948-061001	Application No. 09/778,013
	Applicant Terry Strom, et al.	
	Filing Date February 6, 2001	Group Art Unit 1645 1637

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### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
J. H.	AR	Almond, et al. <i>Risk Factors for Chronic Rejection in Renal Allograft Recipients</i> . Transplantation 55(4):752-757 (Apr. 1993).
	AS	Alpert, et al. <i>The Relationship of Granzyme A and Perforin Expression to Cardiac Allograft Rejection and Dysfunction</i> . Transplantation 60(12):1478-1485 (Dec. 1995).
	AT	Amersi, et al. <i>Upregulation of heme oxygenase-1 protects genetically fat Zucker rat livers from ischemia/reperfusion injury</i> . J. Clin. Invest. 104:1631-1639 (1999).
	AU	Atkinson, et al. <i>Cytotoxic T Lymphocyte-assisted Suicide</i> . J. Biological Chemistry 273(33):21261-21266 (1998).
	AV	Bach, et al. <i>Accommodation of vascularized xenografts: expression of "protective genes" by donor endothelial cells in host Th2 cytokine environment</i> . Nature Medicine 3(2):196-204 (Feb. 1997).
	AW	Bach, et al. <i>Protective genes expressed in endothelial cells: a regulatory response to injury</i> . Immunology Today, Oct. 1997.
	AX	Badrichani, et al. <i>Bcl-2 and Bcl-X<sub>L</sub> serve an anti-inflammatory function in endothelial cells through inhibition of NF-<math>\kappa</math>B</i> . J. Clin. Invest. 103(4):543-553 (1999).
	AY	Beckingham, et al. <i>Analysis of factors associated with complications following renal transplant needle core biopsy</i> . British Journal of Urology 73:13-15 (1994).
	AZ	Benfield, et al. <i>Safety of kidney biopsy in pediatric transplantation</i> . Transplantation 67(4):544-547 (Feb. 1999).
	AAA	Berke. <i>Unlocking the secrets of CTL and NK cells</i> . Immunology Today 16(7):343-346 (1995).
	ABB	Boise, et al. <i>bcl-x, a bcl-2-Related Gene That Functions as a Dominant Regulator of Apoptotic Cell Death</i> . Cell 74:597-608 (Aug. 1993).
	ACC	Carraway, et al. <i>Expression of heme oxygenase-1 in the lung in chronic hypoxia</i> .
	ADD	Clement, et al. <i>Perforin and Granzyme B Expression is Associated with Severe Acute Rejection</i> . Transplantation 57(3):322-326 (Feb. 1994).
	AEE	Choi, et al. <i>Heme Oxygenase-1: Function, Regulation, and Implication of a Novel Stress-inducible Protein in Oxidant-inducing Lung Injury</i> . Amer. J. of Respiratory Cell and Molecular Biology 15:9-19 (1996).
	AFF	Colvin, et al. <i>Evaluation of Pathology Criteria for Acute Renal Allograft Rejection: Reproducibility, Sensitivity, and Clinical Correlation</i> . J. Am. Soc. Nephrol. 8:1930-1941 (1997).
	AGG	Cooper, et al. <i>A20 Blocks Endothelial Cell Activation through a NF-<math>\kappa</math>B-dependent Mechanism</i> . Journal of Biological Chemistry 271(30):18068-18073 (1996).
	AHH	Cooper, et al. <i>A20 Expression Inhibits Endothelial Cell Activation</i> . Transplantation Proceedings, Barcelona, Aug. 1996.
	AII	DeBruyne, et al. <i>Gene Transfer of Immunomodulatory Peptides Correlates with Heme Oxygenase-1 Induction and Enhanced Allograft Survival</i> . Transplantation 69(1):120-128 (2000).
	AJJ	Dong, et al. <i>Heme Oxygenase-1 in Tissue Pathology</i> . American Journal of Pathology 156(5):1485-1488 (2000).
	AKK	Ferran, et al. <i>A20 Inhibits NF-<math>\kappa</math>B Activation in Endothelial Cells Without Sensitizing to Tumor Necrosis Factor-Mediated Apoptosis</i> . Blood 91(7):2249-2258 (1998).
J. H.	ALL	Gaber, et al. <i>Correlation of histology to clinical rejection reversal: A Thymoglobulin Multicenter Trial report</i> . Kidney International 55:2415-2422 (1999).

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Application No.

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## Information Disclosure Statement

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Applicant

Terry Strom, et al.

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Filing Date

February 6, 2001

Group Art Unit

1645 / 637 TECH CENTER 1600/21

## Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
J. Z.	AMM	Gulanikar, et al. <i>The incidence and impact of early rejection episodes on graft outcome in recipients of first cadaver kidney transplants.</i> Transplantation 53(2):323-328 (1992).
	ANN	Hancock, et al. <i>Antibody-induced transplant arteriosclerosis is prevented by graft expression of anti-oxidant and anti-apoptotic genes.</i> Nature Medicine 4(12):1392-1396 (1998).
	AOO	Hariharan, et al. <i>Improved graft survival after renal transplantation in the United States, 1988 to 1996.</i> The New England Journal of Medicine 342(9):605-612 (2000).
	APP	Henkart. <i>Lymphocyte-Mediated Cytotoxicity: Two Pathways and Multiple Effector Molecules.</i> Immunity 1:343-346 (1994).
	AQQ	Heusel, et al. <i>Cytotoxic Lymphocytes Require Granzyme B for the Rapid Induction of DNA Fragmentation and Apoptosis of Allogenic Target Cells.</i> Cell 76:977-987 (1994).
	ARR	Huraib, et al. <i>Percutaneous Needle Biopsy of the Transplanted Kidney: Technique and Complications.</i> American Journal of Kidney Diseases 14(1):13-17 (1989).
	ASS	Kagi, et al. <i>Cytotoxicity mediated by T cells and natural killer cells is greatly impaired in perforin-deficient mice.</i> Nature 369:31-37 (1994).
	ATT	Kagi, et al. <i>Molecular mechanisms of lymphocyte-mediated cytotoxicity and their role in immunological protection and pathogenesis in vivo.</i> Annu. Rev. Immunol. 14:207-232 (1996).
	AUU	Krams, et al. <i>Expression of the cytotoxic T cell mediator granzyme B during liver allograft rejection.</i> Transplant Immunology 3:162-166 (1995).
	AVV	Lee, et al. <i>Overexpression of heme oxygenase-1 in human pulmonary epithelial cells results in cell growth arrest and increased resistance to hyperoxia.</i> Proc. Natl. Acad. Sci. USA 93:10393-10398 (1996).
	AWW	Legros-Maida, et al. <i>Granzyme B and perforin can be used as predictive markers of acute rejection in heart transplantation.</i> Eur. J. Immunol. 24:229-233 (1994).
	AXX	Lin, et al. <i>Accommodated Xenografts Survive in the Presence of Anti-donor Antibodies and Complement That Precipitate Rejection of Naïve Xenografts.</i> Journal of Immunology 163:2850-2857 (1999).
	AYY	Lindholm, et al. <i>The impact of acute rejection episodes on long-term graft function and outcome in 1347 primary renal transplants treated by 3 cyclosporine regimens.</i> Transplantation 56(2):307-315 (1993).
	AZZ	Lipman, et al. <i>Heightened Intragraft CTL Gene Expression in Acutely Rejecting Renal Allografts.</i> Journal of Immunology 152:5120-5127 (1994).
	AAAA	Littell, et al. <i>SAS<sup>®</sup> System for Mixed Models.</i> SAS Institute, Inc. (1996).
	ABBB	Liu, et al. <i>Perforin: structure and function.</i> Immunology Today 16(4):194-201 (1995).
	ACCC	Maines. <i>The Heme Oxygenase System: A regulator of second messenger gases.</i> Annu. Rev. Pharmacol. Toxicol. 37:517-554 (1997).
	ADDD	Nath, et al. <i>Induction of Heme Oxygenase is a Rapid, Protective Response in Rhabdomyolysis in the Rat.</i> J. Clin. Invest. 90:267-270 (1992).
	AEEE	Nath, et al. <i>The Indispensability of Heme Oxygenase-1 in Protecting Against Acute Heme Protein-Induced Toxicity in Vivo.</i> American Journal of Pathology 156(5):1527-1535 (2000).
↓	AFFF	Nicholson, et al. <i>A prospective randomized trial of three different sizes of core-cutting needle for renal transplant biopsy.</i> Kidney International 58:390-395 (2000).

Examiner Signature



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EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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U.S. Department of Commerce  
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Attorney's Docket No.

01948-061001

Application No.

09/778,013

Information Disclosure Statement  
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Applicant

Terry Strom, et al.

Filing Date

February 6, 2001

Group Art Unit

1645-637

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## Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
J. Ty	AGGG	Ohta, et al. <i>Tubular Injury as a Cardinal Pathologic Feature in Human Heme Oxygenase-1 Deficiency</i> . American Journal of Kidney Diseases 35(5):863-870 (2000).
	AHHH	Opipari, et al. <i>The A20 cDNA Induced by Tumor Necrosis Factor <math>\alpha</math> Encodes a Novel Type of Zinc Finger Protein</i> . Journal of Biological Chemistry 265(25):14705-14708 (1990).
	AIII	Opipari, et al. <i>The A20 Zinc Finger Protein Protects Cells from Tumor Necrosis Factor Cytotoxicity</i> . Journal of Biological Chemistry 267(18):12424-12427 (1992).
	AJJJ	Otterbein, et al. <i>Carbon monoxide has anti-inflammatory effects involving the mitogen-activated protein kinase pathway</i> . Nature Medicine 6(4):422-428 (2000).
	AKKK	Racusen, et al. <i>The Banff 97 working classification of renal allograft pathology</i> . Kidney International 55:713-723 (1999).
	ALLL	Rush, et al. <i>Histological findings in early routine biopsies of stable renal allograft recipients</i> . Transplantation 57(2):208-211 (1994).
	AMMM	Rush, et al. <i>Beneficial Effects of Treatment of Early Subclinical Rejection: A Randomized Study</i> . J. Amer. Soc. Nephrol. 9:2129-2134 (1998).
	ANNN	Sarma, et al. <i>Activation of the B-cell Surface Receptor CD40 Induces A20, a Novel Zinc Finger Protein That Inhibits Apoptosis</i> . Journal of Biological Chemistry 270(21):12343-12346 (1995).
	AOOO	Schulz, et al. <i>Acute rejection of vascular heart allografts by perforin-deficient mice</i> . Eur. J. Immunol. 25:474-480 (1995).
	APPP	Sharma, et al. <i>Molecular Executors of Cell Death-Differential Intrarenal Expression of Fas Ligand, Fas, Granzyme B, and Perforin during acute and/or chronic rejection of human renal allografts</i> . Transplantation 62(12):1860-1866 (1996).
	AQQQ	Shoskes, et al. <i>Deleterious effects of delayed graft function in cadaveric renal transplant recipients independent of acute rejection</i> . Transplantation 66(12):1697-1701 (1998).
	ARRR	Smyth. <i>Dual mechanisms of lymphocyte-mediated cytotoxicity serve to control and deliver the immune response</i> . Bioessays 17(10):891-898 (1995).
	ASSS	Smyth, et al. <i>Granzymes: exogenous proteinases that induce target cell apoptosis</i> . Immunology Today 16(4):202-206 (1995).
	ATTT	Soares, et al. <i>Expression of heme oxygenase-1 case determine cardiac xenograft survival</i> . Nature Medicine 4(9):1073-1077 (1998).
	AUUU	Sorof, et al. <i>Histopathological concordance of paired renal allograft biopsy cores</i> . Transplantation 60(11):1215-1219 (1995).
	AVVV	Strehlau, et al. <i>Quantitative detection of immune activation transcripts as a diagnostic tool in kidney transplantation</i> . Proc. Natl. Acad. Sci. USA 94:695-700 (1997).
	AWWW	Strom, et al. <i>Identity and cytotoxic capacity of cells infiltrating renal allografts</i> . New England Journal of Medicine 292(24):1257-1263 (1975).
	AXXX	Suthanthiran, et al. <i>Excellent outcome with a calcium channel blocker-supplemented immunosuppressive regimen in cadaveric renal transplantation</i> . Transplantation 55(5):1008-1013 (1993).
	AYYY	Suthanthiran, et al. <i>Renal Transplantation</i> . New England Journal of Medicine 331(6):365-376 (1994).
✓	AZZZ	Tewari, et al. <i>Lymphoid expression and regulation of A20, an inhibitor of programmed cell death</i> . Journal of Immunology 154:1699-1706 (1995).

Examiner Signature

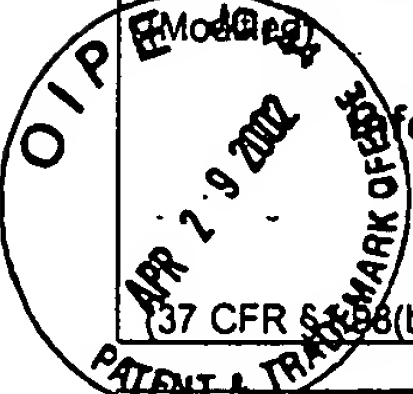
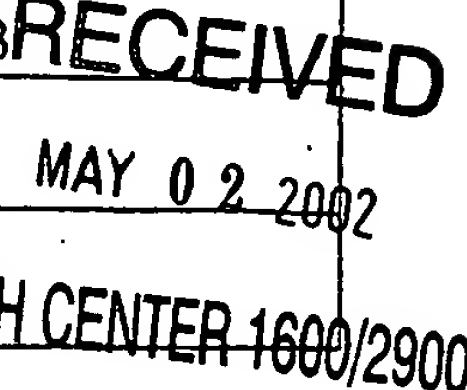
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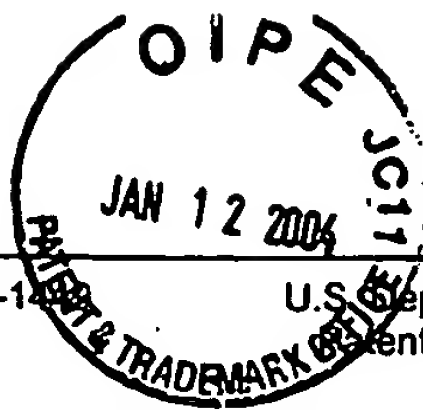
Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 01948-061001	Application No. 09/778,013
<b>Information Disclosure Statement</b> <b>by Applicant</b> (Use several sheets if necessary) (37 CFR § 1.58(b))				Applicant Terry Strom, et al.	
				Filing Date February 6, 2001	
				Group Art Unit 1645	

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
J-T	AAAAA	Vogt, et al. <i>Glomerular Inflammation Induces Resistance to Tubular Injury in the Rat.</i> J. Clin. Invest. 98:2139-2145 (1996).
	ABBBB	Willis, et al. <i>Heme oxygenase: a novel target for the modulation of the inflammatory response.</i> Nature Medicine 2(1):87-90 (1996).
	ACCCC	Yachie, et al. <i>Oxidative stress causes enhanced endothelial cell injury in human heme oxygenase-1 deficiency.</i> Journal of Clinical Investigation 103(1):129-135 (1999).
✓	ADDDD	Yoshida, et al. <i>Human heme oxygenase cDNA and induction of its mRNA by hemin</i> Eur. J. Biochem. 171:457-461 (1988).

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	Applicant Terry Strom et al.		
	Filing Date February 6, 2001	Group Art Unit <del>1645</del> 1637	

U.S. Patent Documents							
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	AJ						
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							Yes	No
	AL							
	AM							
	AN							
	AO							
	AP							

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J.T	AQ	D.R. Jeyarajah et al., "Changes in Urinary Cytokine mRNA Profile After Successful Therapy for Acute Cellular Renal Allograft Rejection," <i>Transplantation Proceedings</i> 27:887-889 (1995).
J.T	AR	J. Strehlau et al., "Quantitative Detection of Immune Activation Transcripts as a Diagnostic Tool in Kidney Transplantation," <i>Pro. Natl. Acad. Sci. USA</i> 94:695-700 (1997).
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	Applicant <b>Terry Strom et al.</b>			
	Filing Date <b>February 6, 2001</b>		Group Art Unit <b>1637</b>	

**U.S. Patent Documents**


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	AA						
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<b>J.T</b>	AK	Strehlau et al., "Quantitative detection of immune activation transcripts as a diagnostic tool in kidney transplantation," Proc. Natl. Acad. Sci. USA, 94:695-700 (1997)
<b>u "</b>	AL	Jeyarajah et al., "Changes in Urinary Cytokine mRNA Profile after Successful Therapy for Acute Cellular Renal Allograft Rejection," Transplantation Proceedings, 27:887-889 (1995)

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